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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,752	01/17/2002	Norbert A. Gschwend	33809	9021

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 08/12/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/889,752	Gschwend et al.
Examiner	**Art Unit**
Michele Flood	1651

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 17, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-15* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. In the instant case, the language “The invention relates” should be avoided.

Claim Objection

Claims 4-15 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other dependent claim. See MPEP § 608.01(n).

Although Claims 4-15 have been objected to under 37 CFR 1.75(c), all of the claims have been considered on the merits to expedite prosecution of the case, as set forth below. The claims have been examined, as if they properly depended from Claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase "as well as" because the phrase is somewhat awkward and it is unclear whether the limitation(s) following the phrase are part of the claimed invention. It is suggested that the phrase "as well as" be deleted from the claim language and replaced with the linking term, and, to conform with standard U.S. practice.

Claim 2 recites the limitation "employed" in line 2. The claim lacks clear antecedent basis for this limitation. Applicant may overcome the rejection by deleting the limitation from the claim language of Claim 2.

Claims 3 and 8 are rendered vague and indefinite by the term "preferably". A broad range or limitation followed by linking terms (preferably, for instance, for example, maybe, especially) and a narrow range or limitation with the broad range or limitation is considered indefinite since the resulting claims does not clearly set forth the metes and bounds of the patent protection desired (see MPEP 2173.05(c) for additional information.)

Regarding claims 1-8, 11, 12 and 14-15, the phrase "especially" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding Claim 8, line 8, the linking term, and, should be placed at the end of the line to place the claim in proper grammatical form.

Claims 9 and 10 appear to provide for the use of (i.e., the cutaneous form of administration of employing a pharmaceutical preparation), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Accordingly, Claims 9 and 10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 12 recites the limitations "the first phase" and the "second phase" in lines 1 and line 3, respectively. There is insufficient antecedent basis for these limitations in the claim. Applicant may overcome the rejection by replacing "phase" with step in these phases.

Claim 13 is rendered indefinite by the phrases "mixed", "added", "blended", and "screened" because the limitations of a claim should be drafted to include a positive statement. For instance, Applicant may overcome the rejection by replacing the phrases with mixing, adding, blending, and screening.

Claim 13 recites the limitation "the first phase" in lines 1, 4 and 5. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "phase" with step in these phrases.

Claim 13 recites the limitation "the components" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Regarding Claims 13 and 14, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 14 appears to provide for the use (i.e., the application) of the process per one of the claims 11 to 13 for producing a foot powder suitable to treat rheumatic syndromes, but, since

the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 15 provides for the use of the pharmaceutical per one of the claims 1 to 8 for treating recited disorders or ailments, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F.6 Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-15 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors, as set forth below:

For instance, Claims 1-8 recite "Pharmaceutical composition" and Claims 11-13 recite "Process" without placing an article before the terms. Applicant may place the article A before each term then replace the capital letter "P" with a lower case letter to place the claims in proper grammatical form.

For instance, Claim 11 recites the idiomatic phrase 'so-called "catalytic powder"'in line 3, and it is suggested that the phrase "so-called" and the parentheses enclosing the term "catalytic powder" (which also appears in Claim 12) be deleted from the claim language of Claim 11 to place the claim in proper form.

For instance, Claim 15, line 3, capitalizes the term "Sciatica". It is suggested that the capital "S" appearing in the term be replaced with a lower case s, as the term is not a proper noun.

The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: In re Steele, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); In re Moore 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); In re Merat, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljunggren (P) and/or Mallasz (A) in view of Gruenweld et al. (U), Kovacs (NN, HU 77312T), Li (JJ, CN 1130074), Stevens (B), McCarthy (S), Zimmer (T), Shen (II, CN 1174061), Borbely et al. (N, Abstract), Murase et al. (O), Vittone (C) and BE 723594 (Q), Iordachel et al. (R) and Lust (V).

Applicant claims a pharmaceutical composition for treating rheumatic syndromes containing at least the following active ingredients: sulfur, mustard and cupric salt. Applicant further claims a pharmaceutical composition according to claim 1, wherein the cupric salt is copper sulfate. Applicant further claims a pharmaceutical composition according to claim 1

further containing camomile. It appears that Applicant further claims methods of making and methods of using the instantly claimed pharmaceutical composition.

Ljunggren teaches a pharmaceutical composition for treating rheumatism and dermatosis comprising FeS (0.1 to 5%); FeS (0 to 4%) and sulphur (0 to 4%), which was prepared by mixing the dry substances with an inert dispersing agent and was applied directly to the diseased spot. Mallasz also teaches an anti-rheumatic pharmaceutical composition comprising sulfur, and a method of making thereof. The referenced composition comprises one or more metallic substances (e.g., copper and sulfur), which is used as an antispasmatic product for the treatment of rheumatism and related rheumatic disorders (see Column 2, lines 4-16; Column 3, lines 46-59; and Column 7, lines 8-24). The compositions taught by Mallasz are in the form of various conventional pharmaceuticals, i.e., powder, liquid, gas and/or mixtures thereof, adhesive tapes, and plasters. In Column 8, lines 50-67, Mallasz teaches a "Rheumatic plaster" comprising sulphur and copper in various dose amounts. See the tables in Column 9, wherein Mallasz shows how effective the copper/sulfur plaster is in treating various rheumatic syndromes.

The teachings of Ljunggren and Mallasz are set forth above. Neither Ljunggren nor Mallasz teach a pharmaceutical preparation further comprising mustard seed, a cupric salt, camomile, camphor, and potassium iodate. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed ingredients to the sulfur-containing pharmaceutical preparation(s) taught by Ljunggren and/or Mallasz in the making of the claimed composition having the claimed functional effect for

treating rheumatic syndromes because each of the references of Greunweld, Kovacs, Li and Stevens teach compositions comprising mustard seed that are used for treating rheumatic syndromes, each of the references of McCarthy, Zimmer and Shen teach compositions comprising a cupric salt that are used for treating rheumatoid illnesses, each of the references of Borbely and Murase teach compositions comprising camomile that are used for treating rheumatic syndromes, each of the references of Vittone and BE 723594 teach compositions comprising camphor that are used for treating rheumatic syndromes, and Iordachel teaches a composition comprising potassium iodate that is used treating rheumatic syndromes. For instance, Gruenweld teaches a method of making an external antirheumatic preparation comprising a mustard plaster comprising mixing 100 g of mustard flour with lukewarm water and packing the plaster in linen. See page 698, Column 2, lines 1-6. Secondly, Kovacs teaches a rheumatic and muscular painkilling cream composition comprising 0.51- 0.60 of white mustard seeds. Thirdly, Li teaches a medicinal powder comprising white mustard seed, which is prepared by mixing, crushing, and sieving herbs, then filling a non-woven cloth bag with the powdered mixture. The medicinal powder taught by Li is soaked in warm water, then directly applied to the affected area and is effective in the treatment of rheumatism, and related rheumatic syndromes. Finally, Stevens teaches a topical foot powder comprising the seeds of either black mustard or white mustard in the amount of 0 to 40%, preferably in amount of about 3% to about 40%, and more preferably 20% to about 40% of the total weight of the composition (see Column 2, lines 53-62), which imparts warmth to the skin when applied externally. In Column 1, lines

34-46, Stevens teaches that preparations which provide a sense of warmth to painful areas of the body are based on counterirritants such as mustard and camphor, and that these ingredients are recommended for treatment for muscle pain and arthritis.

With regard to cupric salts, both McCarthy and Zimmer teach topical compositions comprising copper sulfate, which are used for treating rheumatic syndromes, such as inflammatory and arthritic conditions. Furthermore, Shen teaches a method of making a Chinese medicine capsule for rheumatoid diseases comprising grinding, mixing and capsulizing herbal ingredients with calcined native copper. Shen teaches that the composition can be administered over a long period of time without toxic side effects and has a curative effect.

With regard to camomile, Borbely teaches an antirheumatic ointment comprising camomile oils (*Matricaria chamomilla*). Secondly, Murase teaches a pharmaceutical preparation that comprises an herbal extract of plants obtained from the body parts of the plant *Matricaria chamomilla*, which is used in the treatment of rheumatism and gout. Moreover, with regard to the claim limitation of Claim 3 wherein it appears that the invention is directed to a pharmaceutical preparation wherein the added camomile is in the form of camomile flowers, it also would have been obvious to one of ordinary skill in the art and one of ordinary skill in the art would have been have been motivated and would have had a reasonable expectation of success to add the claimed camomile ingredient in the form of flowers because at the time the invention was made it was well known in the art that camomile flowers are the medicinal part of the camomile plant, as evidenced by the teachings of Lust on page 144 under the headings

"CAMOMILE (a) (*Anthemis nobilis)*" and "CAMOMILE (b) (*Matricaria chamomilla)*". Lust also teaches, on page 144, lines 24-25, that "The flowers can also be made into a rubbing oil for swellings, callouses, and painful joints." Further note that on page 287, Lust teaches the use of mustard (*Brassica spp.*) in cases of rheumatism, sciatica, peritonitis, neuralgia, and various internal inflammations. Furthermore, on page 288, lines 1-10, Lust teaches a method of making and the use of a mustard powder plaster for application to the skin.

With regard to camphor, Vittone teaches an external composition comprising 10/16 ounces of camphor and 1/16 ounces of mustard oil, which is used of the treatment of inflammation of joints as in arthritis, bone degeneration and bursitis. Similarly, BE 723594 teaches topical compositions containing (0.2-1%) camphor for the treatment of rheumatism, eczema, aches, and sunburns.

Finally, with regard to potassium iodate, Iordachel teaches a wound-healing promoting agent comprising potassium iodate.

At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of adding any of the pharmaceutical preparations comprising mustard seed taught by Greunweld, Kovacs, Li and Stevens, adding any of the pharmaceutical preparations comprising cupric salts taught by McCarthy, Zimmer and Shen, adding any of the pharmaceutical preparations comprising camomile taught by Borbely and Murase, adding any of the pharmaceutical preparations comprising camphor taught by Vittone and BE 723594, and adding the pharmaceutical

preparation comprising potassium iodate taught by Iordachel to the pharmaceutical preparation taught by Ljunggren and/or Mallasz to provide the claimed invention because mustard seed, cupric salts, camomile, camphor, and potassium iodate were known as ingredients having the beneficial functional effect of treating rheumatic syndromes, as evidenced by the referenced teachings.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. Thus, at the time the invention was made, one of ordinary skill in the at would have been motivated and one would have had a reasonable expectation of success to add any of the claimed ingredients taught by either Ljunggren and/or Mallasz to the claimed ingredients taught by Gruenweld, Kovacs, Li, Stevens, McCarthy, Zimmer, Shen, Borbely, Murase, Vittone, BE 723594, and Iordachel in the making of the claimed pharmaceutical preparations having the claimed functional effect because

the claimed invention is no more than the combining of well known ingredients used in well known methods for the treatment of rheumatic syndromes, as further evidenced by the teachings of Lust.

With regard to Claims 9-15, wherein it appears that Applicant claims process steps in the making of the claimed pharmaceutical preparations and methods of use thereof, the references are relied upon for the reasons set forth above. The combined teachings of the cited references set forth above do not appear to teach the particular process steps and/or equipment instantly claimed (although Claims 9-15 are very unclear, as drafted - see USC 112, second paragraph above). However, the adjustment of particular working conditions (e.g., determining the result-effective ratio of ingredients to an additive such as "talc" in the making of pharmaceutical forms for administration; as well as the amount and/or duration of the pharmaceutical preparation to be administered based upon the form of the pharmaceutical preparation to be used- e.g., foot powder, plaster, poultice, capsules, etc. - such as beneficially disclosed by one or more of the cited references; as well as the particular equipment and the order of mixing, screening and blending the ingredients to be used in the making of the pharmaceutical - e.g., "a 4-way mixer"), is deemed merely a judicious selection and routine optimization which would have been well in the purview of either one of ordinary skill in the art or the skilled artisan at the time the invention was made.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

Michele C. Flood

MCF

August 8, 2002